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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,827	03/27/2007	Akira Hayasaka	14875-158US1 C1-A0319-P U	1961
26161	7590	12/19/2008	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1656	
			NOTIFICATION DATE	DELIVERY MODE
			12/19/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/574,827	HAYASAKA ET AL.	
	Examiner	Art Unit	
	CHIH-MIN KAM	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/12/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-2 and 4-11 are pending.

Applicants' amendment filed September 11, 2008 is acknowledged. Applicants' response has been fully considered. Claims 1, 2 and 4 have been amended, claim 3 has been cancelled, and new claims 5-11 have been added. Therefore, claims 1-2 and 4-11 are examined.

Withdrawn Claim Rejections -- 35 USC § 102

2. The previous rejection of claims 1-2 and 4 under 35 U.S.C. 102(b) as being anticipated by Molina *et al.* (Food research International, 32 (1999), pages 135-143), is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 6 in the amendment filed September 11, 2008.

3. The previous rejection of claims 1-2 and 4 under 35 U.S.C. 102(b) as being anticipated by Flink (WO 99/37329), is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 6 in the amendment filed September 11, 2008.

Withdrawn Claim Rejections -- 35 USC § 103

4. The previous rejection of claim 3 under 35 U.S.C. 103(a) as being unpatentable over Flink (WO 99/37329), is withdrawn in view of applicants' cancellation of the claim, and applicants' response at pages 6-8 in the amendment filed September 11, 2008.

New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 1, 2 and 4-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 2 and 4-11 are directed to a method for stabilizing an IgM, wherein the method comprises adding a citric acid buffer to a first solution comprising the IgM to form a second solution comprising the IgM at a concentration of 20 mg/ml or greater, wherein the IgM is stabilized at low temperature, e.g., at about 7, about 4 or about 1 °C.

While the specification discloses the effect of citric acid buffer on the stability of IgM at various concentrations and at three specific low temperatures (i.e., at 1, 4 or 7 °C; Figs. 1-4; page 4, lines 13-20; Examples 1-3), the specification does not disclose measuring the effect of citric acid buffer on the stability of IgM at any low temperature, or at about 1, about 4 or about 7 °C. Measuring the stabilizing effect of citric acid buffer on IgM at 1, 4 or 7 °C does not provide sufficient written description for measuring the stabilizing effect of citric acid buffer at any low temperature, e.g., at -20 °C. Without guidance on the definition of “low temperature” and “about”, one skilled in the art would not know at what low temperature the stabilizing effect of citric acid buffer on IgM is measured, and what stabilizing effect is obtained at this low temperature. The lack description on the terms “low temperature” and “about”, and the lack of representative species as encompassed by the claims, applicants have failed to sufficiently

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describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2 and 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 2 and 4-11 are indefinite because of the use of the term “low temperature” or “about”. The term cited renders the claim indefinite, it is unclear what are the metes and bounds for the term “low temperature” or “about”. Claims 2 and 4-11 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Conclusions

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chi-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

December 12, 2008